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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/714,567	11/14/2003	Paul Wentworth	1361.028US1	1768

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EXAMINER	
VENCI, DAVID J	

ART UNIT	PAPER NUMBER
1641	

DATE MAILED: 09/01/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/714,567	WENTWORTH ET AL.	
	Examiner	Art Unit	
	David J. Venci	1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *June 9, 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-3,5-13 and 15-44* is/are pending in the application.

4a) Of the above claim(s) *11-13 and 15-44* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-3 and 5-10* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-3,5-13 and 15-44* are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *06/09/06*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action is withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on April 12, 2006, is entered.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Election/Restrictions

Amended claims 11-13 and 15-20 are directed to an invention that is independent or distinct from the invention originally claimed and examined. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claim 1-3 and 5-10, drawn to a method comprising an analysis step to detect an "antibody response", classified in class 436/517, for example.

II. Claims 11-13 and 15-20, drawn to a method comprising an analysis step to detect an "antibody-generated inflammatory response", classified in class 424/9.2, for example.

III. Claims 21-44, drawn to a method for assaying neutrophil activity, classified in class 435/7.21, for example.

The inventions are distinct, each from the other because of the following reasons:

Inventions (I or II) and III are independent and patentably distinct. Inventions are independent and patentably distinct if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the different inventions have different modes of operation because Inventions (I or II) require a step of administering a chemical probe, while Invention III requires the step of activating neutrophils.

Inventions I and II are related processes. Related processes are distinct from each other if the inventions, as claimed, are not: (1) overlapping in scope, i.e., are mutually exclusive; (2) obvious variants; and (3) capable of use together or have a materially different design, mode of operation, function, or effect. See MPEP § 806.05(j).

With respect to (1), *supra*, the inventive feature of Inventions I and II is a step of "analyzing the sample for an oxidized chemical probe". However, the scope of Inventions I and II does not overlap because the

step of "analyzing the sample for an oxidized chemical probe" is different in each Invention. For example, Inventions I requires a step of analyzing to detect an "antibody response", while Invention II requires a step of analyzing to detect an "antibody-generated inflammatory response".

With respect to (2), *supra*, Inventions I and II are not obvious variants because detecting an "antibody response and detecting an "antibody-generated inflammatory response" involve different assays with different endpoints. Furthermore, there is no indication on the record that the Inventions would have been obvious variants over each other within the meaning of 35 U.S.C. 103(a).

With respect to (3), *supra*, Inventions I and II have different modes of operation because Invention I requires, *inter alia*, a quantitative protein determination, while Invention II requires, *inter alia*, a qualitative commercial determination.

Examination burden is established because the scope of prior art search required for each Invention does not appear coextensive. For example, a search for the commercial assays involved in Invention I requires a search of prior art related to immunoassays, while a search for the quantitative endpoint of Invention II requires a search of prior art related to pain, heat, redness and swelling.

As indicated, *supra*, restriction for examination purposes is proper because the inventions are distinct and require separate, non-coextensive searches of the prior art.

Applicant has received an action on the merits for originally presented Invention I, corresponding to claims 1-3 and 5-10 of the instantly pending claims. Accordingly, claims 1-3 and 5-10 have been constructively elected by original presentation for prosecution on the merits.

Herein, claims 11-13 and 15-20 are withdrawn from consideration as being directed to a non-elected invention. Claims 21-44 remain withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Currently, claims 1-3 and 5-10 are under examination.

Specification

The disclosure is objected to because of the following informalities:

Throughout the specification, reference to the conversion of "singlet oxygen" into "reactive oxygen species" appears repugnant to the art-recognized definition of "reactive oxygen species" because persons skilled in the art generally do not recognize "singlet oxygen" as a separate genus, but rather recognize that "singlet oxygen" belongs to the broader genus of "reactive oxygen species." Furthermore:

On p. 24, lines 27-28, the phrase "[t]he role of the newly discovered chemical potential of antibodies [to generate reactive oxygen species] *in vivo* is dependent on the availability of the key substrate $^1O_2$*" (paraphrasing mine) is indefinite in view of p. 18, lines 4-5 phrase "the term 'reactive oxygen species' means antibody-generated oxygen species".

On p. 30, line 13, the phrase "[i]n the present invention, the minimum requirements are singlet oxygen, an antibody reagent..." (paraphrasing mine) is indefinite in view of p. 18, lines 4-5 phrase "the term 'reactive oxygen species' means antibody-generated oxygen species".

Appropriate correction is required.

Claim Rejections - 35 USC § 112 – second paragraph

Claims 1-3 and 5-10 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 1:

In step (a), the phrase "antibody-generated reactive oxygen species" is indefinite. Whether one or more steps of "generating" reactive oxygen species is completed, performed, or merely intended is not clear.

Claim 1 appears to omit essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. Specifically, the identity of one or more objects and/or steps required for "generating" reactive oxygen species with an antibody is not clear and appear omitted from the claim. According to Applicants' specification, antibodies generate hydrogen peroxide *in vitro* in the presence of a source of $^1O_2$ in PBS pH 7.4 (see specification, p. 46, lines 22-26) as detected by an Amplex® Red hydrogen peroxide assay kit from Invitrogen, Inc. (see specification, p. 45, lines 17-20). Whether/what additional steps are required for "generating" reactive oxygen species with an antibody is not clear. Whether/how additional steps of generating hydrogen peroxide *in vitro* in the presence of a source of $^1O_2$ in PBS pH 7.4 are incorporated into the method of claim 1, or the claimed step of "administering to the mammal" is not clear.

In step (c), the infinitive "to detect" is indefinite. Whether the act or process of "detecting" is completed or performed, or merely intended, is not clear. The identity of object(s) and/or step(s), if any, required for performing "detecting" is not clear. Whether the object(s) and/or steps required for performing "analyzing" are coextensive with the object(s) and/or steps required for performing "detecting" is not clear.

In step (c), the phrase "analyzing... an oxidized chemical probe to detect... an antibody response" is indefinite. The proximate relationship between "probe" and "antibody response" is not clear. Whether/how detecting an "antibody response" amounts to analyzing a "probe" is not clear.

In the preamble and in step (c), the term "antibody response" is indefinite and lacks antecedent support in the specification. The identity of necessary and sufficient elements defining "antibody response" is not clear.

Claim Rejections - 35 USC § 102

Claims 1-3 and 5-10 are rejected under 35 U.S.C. 102(b) as being anticipated by Iribarren *et al.*, 17 ARTERIOSCLER. THROMB. VASC. BIOL. 1171 (1997).

Iribarren *et al.* describe a method for detecting an antibody response in a mammal comprising:

(a) administering to the mammal a chemical probe (see p. 1172, right column, *Dietary Intake of Vitamins*) for[1] an antibody-generated reactive oxygen species (see p. 1175, left column, second full paragraph, second sentence "carotenoid pigments have been shown to be efficient quenchers of singlet oxygen generated in solution");

(b) obtaining a sample from the mammal (see p. 1172, *Autoantibodies to Modified LDL*, sixth sentence, "serum"); and

(c) analyzing the sample for an oxidized chemical probe (see p. 1172, right column, *Autoantibodies to Modified LDL*, fourth sentence) to detect whether there is an antibody response in the mammal (see p. 1175, paragraph bridging left and right columns, first sentence, "no significant cross-sectional relation was observed between autoantibodies against MDA-LDL and IMT"); wherein the reactive oxygen species comprise oxygen with one or more unpaired electrons (see p. 1175, left column, second full paragraph, second sentence "singlet oxygen").

[1] With respect to the limitation of a chemical probe "for" an antibody-generated reactive oxygen species, Examiner observes that Iribarren *et al.* describe chemical probes (*i.e.*, vitamins) that inherently quench singlet oxygen generated in solution (see p. 1175, left column, second full paragraph, second sentence). Absent object evidence to the contrary, Examiner posits that said chemical probe is inherently "for" an antibody-generated reactive oxygen species, (claim 1), superoxide radical, hydroxyl radical, peroxyl radical, hydrogen peroxide (claim 5) and ozone (claim 6), and would be so recognized by persons of ordinary skill.

Response to Arguments

In prior Office Action, Examiner objected to the disclosure because, throughout the specification, reference to the conversion of "singlet oxygen" into "reactive oxygen species" appears repugnant to the art-recognized definition of "reactive oxygen species". Examiner posits that persons skilled in the art generally do not recognize "singlet oxygen" as a separate genus, but rather recognize that "singlet oxygen" belongs to the broader genus of "reactive oxygen species."

In response, Applicants argue that the specification at p. 18, lines 4-11 discloses that "singlet oxygen is not a 'reactive oxygen species'." (see Applicants' reply, p. 9, the paragraph beginning "First, the Examiner...", third sentence).

Applicants' argument is not persuasive.

Applicants' specification at p. 18, lines 4-11 does not recite the term "singlet oxygen", much less exclude "singlet oxygen" from the class of compounds known as "reactive oxygen species".

In addition, Applicants' argument belies Applicants' pioneering publication, Wentworth *et al.*, 97 PROC. NATL. ACAD. SCI. USA 10930 (2000), which describes singlet oxygen as a "particularly reactive species" (see p. 10931, right column, second full paragraph, first sentence).

Conclusion

No claims are allowed at this time.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David J. Venci whose telephone number is 571-272-2879. The examiner can normally be reached on 08:00 - 16:30 (EST). If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on 571-272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

David J Venci
Examiner
Art Unit 1641

djv

LONG V. LE 09/22/06
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